REMARKS

Claim 9 is cancelled with this amendment as being directed to a non-elected invention. Applicant reserves the right to file a divisional application. Claims 8, 10, 48, and 50 have been amended. Claim 51 has been cancelled and incorporated into claim 8. Further support for the amendments is found in the existing claims and the specification as discussed below. Accordingly, the amendments do not constitute the addition of new matter. Applicant respectfully requests the entry of the amendments and reconsideration of the application in view of the amendments and the following remarks.

Claim objections

Claims 8, 10 and 46-51 are objected to because claim 8 does not have a preamble. Claim 8 has been amended to include a preamble. Accordingly, this objection may be withdrawn.

Rejection under 35 U.S.C. § 112, second paragraph

Claims 8, 10 and 46-51 are rejected under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 8 and 50 have been amended to address the rejection.

Claim 8 has been amended to include a preamble.

Claims 8 and 50 have been amended to further define the composition. The composition is defined in claim 8 as a "PRP composition" which includes PRP and the permeation enhancer. The term "matrix" in claim 50 has been replaced with "the PRP composition" which finds antecedent basis in claim 8.

Additionally, claim 50 has been amended to clarify the construction of the transdermal patch. Support is found in the published application at paragraph 0094.

Claim 48 has been amended in light of amendments to claim 8.

Claim 10 is amended to correct clerical error.

Reconsideration and withdrawal of the rejection is respectfully requested.

Rejection under 35 U.S.C. § 102(b)

Claims 8 and 10 are rejected under 35 U.S.C. § 102(b) as being anticipated by US 5,599,558 (Gordinier, et al).

This ground of rejection is addressed by amendment of claim 8 to platelet-rich plasma (PRP) in a "PRP composition....wherein the composition is prepared without adding an exogenous activator". Support for the amendment is found in cancelled claim 51 and in the U.S. published application at paragraph 0065 and 0075.

As stated in paragraph 0075, "...in an embodiment of the invention, no or substantially no exogenous activator is present or added as part of the inventive platelet composition, or is used in the preparation of the inventive platelet composition". PRP compositions prepared without an activator have the advantage that undesirable side effects associated with the use of an activator, such as contamination with viruses, prions, and bacteria, pain and unintentional clotting (as discussed in the U.S. published application at paragraphs 0074 and 0075) are avoided.

In contrast, Gordinier, et al. teach platelet releasate, which is ***exogenously activated*** platelet-rich plasma. Preparation of platelet releasate and use of an exogenous activator is taught in Example 1 of Gordinier et al. Gordinier, et al. teach activation using thrombin (col. 8, lines 44-45) and also use of other activators (col. 8, lines 53-57).

Furthermore, Gordinier, et al teach treatment of ***wounds*** using platelet releasate which is prepared using an exogenous activator. In contrast, the presently claimed invention is directed to method of preparing a composition for dermatological application to ***skin*** which includes a ***skin permeation enhancer*** and PRP (use of skin permeation enhancer was included in claim 8 as originally filed). Gordinier, et al. do not teach treatment of skin and do not teach use of a skin permeation enhancer as claimed.

In view of Applicant's amendment and arguments, reconsideration and withdrawal of the rejection is respectfully requested.

Rejection under 35 U.S.C. § 103(a)

Claims 8, 10 and 46-51 are rejected under 35 U.S.C. § 103(a) as being unpatentable over US 5,599,558 (Gordinier, et al), US 5,993,804 (Read, et al) and US 5,733,571 (Sackler).

This ground of rejection is addressed by amendment taken with the arguments below.

Gordinier, et al teach treatment of ***wounds*** using platelet releasate which is prepared using an exogenous activator. Read, et al. teach platelets which have been lyophilized onto a surgical aid such as a ***wound dressing***, preferably with a fixative agent. In contrast, the presently claimed invention is directed to method of preparing a composition for dermatological application to ***skin*** which includes a ***skin permeation enhancer*** and PRP.

Gordinier, et al. and Read, et al. teach treatment of wounds, not skin. Accordingly, as both Gordinier, et al. and Read, et al. are directed to wound treatment, neither reference teaches a skin permeation enhancer as claimed. Furthermore, neither reference is directed to PRP as now claimed. Read, et al. teach lyophilized platelets, not PRP. Gordinier, et al. teach platelet releasate. As discussed above, platelet releasate is activated PRP while the present claims are directed to PRP prepared without an exogenous activator. As discussed above, this has the advantage of avoidance of undesirable side effects associated with the use of an activator, such as contamination with viruses, prions, and bacteria, pain and unintentional clotting (as discussed in the U.S. published application at paragraphs 0074 and 0075). Accordingly, the references taken as a whole do not teach all of the elements of the claimed invention.

Sackler merely teaches a transdermal patch and does not remedy the deficiencies of Gordinier, et al. and Read, et al. Sackler is not combinable with Gordinier, et al and Read et al. Sackler teaches the construction of a transdermal patch. One of ordinary skill in the art would not apply a transdermal patch to the wounds of Gordinier, et al. and Read, et al.

Furthermore, it is particularly unexpected that the PRP would be effective in the absence of an exogenous activator. While one of ordinary skill in the art would expect activation to occur on the surface of a wound, it is not predictable that PRP applied to skin with a skin permeation enhancer would be activated without resort to an exogenous activator.

Applicant submits the attached Declaration which shows dramatic increases in proliferation of skin fibroblasts in the presence of unactivated PRP according to the invention. This effect of unactivated PRP on skin cells (fibroblasts) could not have been predicted from the cited references, taken separately or together.

In view of Applicant's amendments and arguments, reconsideration and withdrawal of the above ground of rejection is respectfully requested.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicant is not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

CONCLUSION

In view of Applicants' amendments to the claims and the foregoing Remarks, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any remaining concerns which might prevent the prompt allowance of the application, the Examiner is respectfully invited to contact the undersigned at the telephone number appearing below.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: Sept. 8, 2009

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